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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1655	32

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/981,998	PULST, STEFAN M.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *September 21, 2000; October 16, 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,59 and 61-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *59,61,71-73 and 75* is/are allowed.

6)☒ Claim(s) *1-3, 5-7, 62-70, 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed September 12, 2001.

2. Currently, claims 1-3, 5-7, 59, 61-75 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn.

4. This action contains new grounds of rejection.

Priority

5. The examiner notes that the response asserts that certain parts of certain sequences are deemed earlier priority dates.

For the purpose of clarity, the sequences which are found in the pending claims are provided the following priority dates.

SEQ ID NO: 1 nucleotides 1-516	October 8, 1996
SEQ ID NO: 2 nucleotides 163-4098 (coding portion)	October 8, 1996
SEQ ID NO: 4 nucleotides 50-3454 (coding portion)	May 8, 1997
SEQ ID NO: 4	May 8, 1997
SEQ ID NO: 5	May 8, 1997
SEQ ID NO: 19 (newly added from parent application)	October 8, 1996

It is noted that SEQ ID NO: 19 has been added from the parent application. SEQ ID NO: 19 appears to contain only about 400 amino acids from the 1135 amino acids of the full length mouse SCA2 polypeptide. Thus, SEQ ID NO: 19 appear to be a partial polypeptide for the full length mouse SCA2 polypeptide. While SEQ ID NO: 19 appears

to have priority to October 8, 1996, a claim drawn to a nucleic acid encoding a full length SCA2 polypeptide is enabled only as of May 8, 1997 when the full length mouse polypeptide was described.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6 and newly added Claim 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid which has at least 90% homology to the SCA2 coding portion of SEQ ID NO: 2 and 4 wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO: 3 or 5.

The specification teaches SEQ ID NO: 2 and 4 coding positions.

The specification fails to teaches nucleic acids which are 90% identical with these sequences.

There is not adequate description of the genus nucleic acids which are 90% identical with the coding portions of SEQ ID NO: 2 and 4 wherein the DNA encodes a

polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO: 3 or 5. The specification only discloses two nucleic acids within the scope of the genus: nucleic acids which are 90% identical with these sequences wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO: 3 or 5. The nucleic acids described are not representative of the genus nucleic acids which are 90% identical with these sequences. There is substantial variability among the species of nucleic acids encompassed in the scope of the claim. The specification has also not defined a structural feature of the nucleic acids which would be common to all members of the genus that constitutes a substantial portion of the genus. The claim encompasses allelic variants which have not been described. Furthermore, one of skill in the art would conclude that applicant was not in possession of the claimed "nucleic acids which are 90% identical with these sequences wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO: 3 or 5" because the description of only two members of this genus is not representative of the nucleic acids of the genus and is insufficient to support the claims. Thus, the specification does not adequately provide a written description for nucleic acids which are 90% identical with these sequences.

Response to Arguments

The response traverses the rejection. The response asserts that a person of ordinary skill in the art would not expect substantial variability among the species of

nucleic acids encompassed by the scope of the claims because structurally similar nucleic acids result from the requirement that the nucleic acid have both 90% homology and wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO: 3 or 5. It is noted that the amino acid sequence of each of human and mouse are included within the claims for human and also for the claims only directed to mouse. This argument has been reviewed but is not convincing because many antibodies produced using an amino acid sequence selected from SEQ ID NO: 3 or 5 (human or mouse) would necessarily bind to something which is 90% homologous to the SCA2 of SEQ ID NO: 2. The claims encompass any nucleic acid which is 90% to SEQ ID NO: 2 and wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO: 3 or 5. There is a large quantity of epitopes in common with 90% homology such that this limitation is not very limiting.

Further, the claims read on allelic variants, deletions, insertions, additions, substitutions, silent mutations, neutral polymorphisms among other things. The claims provide no functional language such that the nucleic acid which is 90% similar to SEQ ID NO: 2 or 4 would maintain an activity. As provided in the Written Description Guidelines, Example 9, a claim which recites hybridization and functional language is deemed to meet the written description guidelines because the combination of the highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate. Similarly, Example 14,

homology language is provided given a function is also present. In the examiner, the proteins with 95% identity and possess the specified catalytic activity are described. In contrast, the instant case does not provide any function or activity that may be assayed.

Further, while it is noted that Claims 6 and 69 are directed only to human and mouse nucleic acids, alignment of the sequence with closely related species demonstrates the absence of written description for sequences 90% homologous to the particularly claimed SEQ ID NO:s. As provided by the partial sequence of the chimp, gorilla, rhesus monkey, leaf monkey, baboon, and bonnet monkey, the approximately 300-400 base pair partial sequences are 99, 97, 95, 97, 96, and 94% homologous, respectively before the CAG repeat region and 100, 100, 100, 97, -, 100% homologus following the CAG repeat region. There is a single is a single mismatch over the 200 base pair region upstream of the CAG repeat region between the human and the chimp SCA2 nucleic acid. These very closely related sequences have neither been described nor contemplated in the instant specification. Applicant's claim therefore, but for the word human, clearly encompasses subject matter which was not described in the specification in direct contravention of the decision of the CAFC in Regents of the University of California v. Lilly, where a particular nucleic acid species was not found to provide descriptive support for a broader genus of nucleic acids. This case is directly analogous, because a claim to 90% would encompass other species but for the word "human" in claim 1, and if a human chimeric cell had the chimp, leaf monkey or gorilla sequence, applicant's claim would encompass such a sequence without descriptive support as clearly enunciated in Lilly.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112

7. Claims 1-3, 5-7, 62-70, 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A2) Claims 1-3, 65-67 are indefinite over the recitation "an SCA2 polypeptide". Claims 1-3, 65-67 are indefinite because the designation SCA2 is arbitrary. The instantly disclosed polypeptide could be identified by some other arbitrary name, or the name SCA2 could be arbitrarily used to designate another polypeptide. In fact, SCA2 has also been used to refer to stem cell antigen 2 (see WO 97/18224). Thus, it is unclear whether the claims are drawn to the instant SEQ ID NO: 1-5 or whether the claims are intended to encompass stem cell antigen 2. This rejection may be overcome by providing descriptive characterization of the claimed polypeptide such as a SEQ ID NO: or other functional and structural characterization.

B2) Claims 1-3, 65-67 are indefinite because it is unclear whether the nucleic acid must encode a full length SCA2 polypeptide or rather any part of the SCA2 polypeptide of SEQ ID NO: 1-5. The specification has provided a vague definition of SCA2 which state that the "phrase SCA2 refers to substantially pure native SCA2 protein or recombinantly expressed/produced proteins including variants thereof encoded by mRNA generated by alternative splicing of a primary transcript and further including fragments thereof which retain native biological activity". The definition appears to provide that any variant or any fragment is encompassed within the definition

of SCA2 since it is unclear what native biological activity encompasses. Native biological activity may merely encompass the ability to encode amino acids. The art teaches probes consisting of 10 CAG repeats are provided in the art (see 102 rejection below).

C2) Claim 5, 62-64, 68 is indefinite over the recitation "high stringency" because "high stringency" is a relative term which has various meaning to those skilled in the art. The term "high stringency" in claim 5 is a relative term which renders the claim indefinite. The term "high stringency" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. On page 13 of the specification, moderate stringency has been defined, however, high stringency lacks any specific definition. For the purposes of art rejections, the claims are interpreted to mean higher than moderate stringency. It is presumed that high stringency is greater than moderate stringency such that high stringency requires washes higher than 42 and 65 degrees. Thus the metes and bounds of the claimed invention are unclear.

D2) Claim 68 is directed to a DNA which hybridizes under high stringency conditions to the SCA2 coding portion of SEQ ID NO: 19. It is unclear what the SCA2 coding portion of SEQ ID NO: 19 entails since SEQ IDN O: 19 does not encode for a full length protein. SEQ ID NO: 19 appears only to encode for about 1/3 of the full mouse protein as provided in the instant specification.

E2) Claim 67 is unclear whether the claim is intended to depend from Claim 6 or rather Claim 66. It appears that the claim is intended to limit Claim 66.

F2) Claim 74 is indefinite because it is unclear what the scope of the claim requires. It is unclear whether the claim is intended to claim a nucleic acid consisting of SEQ ID NO: 19 or whether the claim is intended to encompass something greater. The metes and bounds of the claimed invention are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2, 5, 62, 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanpei et al. (Biochemical and Biophysical Research Communications, Vol 212, No. 2, pages 341-346, July 1995).

Sanpei teaches a single stranded fluorochrome-conjugated probe (CAG)10 was used by Taneja to detect expanded CTG repeat transcripts. Sanpei also teaches a single stranded probe containing (CAG)55.

Thus, the CAG repeat probes would hybridize under high stringency conditions to the SCA2 coding portion of nucleotides 1-516 of SEQ ID NO: 1 or 163-4098 of SEQ ID NO: 2 since each of these regions contain a portion of glutamine repeats, namely CAG repeats. Furthermore, since it is unclear what constitutes a SCA2 polypeptide, namely

whether the SCA2 polypeptide requires a full length polypeptide or fragments, the CAG repeats encode a fragment of a SCA2 polypeptide. It is noted that the melting temperature of (CAG)10 is 70 degrees, such that (CAG)10 will hybridize to the coding portion of the recited sequences at high stringency.

9. Claim 1-2, 65-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Brennan (US Pat. 5,474,796, December 1995).

This rejection applies to Claims 1-2, 65-66 based upon the unclear definition of an SCA2 polypeptide (see 112/2nd rejection above).

Brennan teaches an array containing oligonucleotides having 10 nucleotides each (10-mers). The array represents every possible permutation of the 10-mer oligonucleotides. Thus, Brennan inherently teaches numerous nucleic acids which hybridize under high stringency conditions to SEQ ID NO: 19 wherein the isolated nucleic acid encodes a fragment of a SCA2 polypeptide. For example, the array of Brennan inherently contains atgcgctcag which are the first 10 coding nucleotides of SEQ ID NO: 1 and thus encode a fragment of a SCA2 protein.

Allowable Subject Matter

10. Claims 59, 61, 73, 75 are allowable over the art. The prior art does not teach the SCA2 nucleic acid from the mouse which are SEQ ID NO: 4 and 5 (limitations of Claims 59 and 61).

11. Claims 71, 72 directed to SCA2 nucleic acids of nucleotides 163-4098 of SEQ ID NO: 2 and encoding the amino acid sequence of SEQ ID NO: 3 are allowable.

12.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
November 27, 2001

JEFFREY FREDMAN
PRIMARY EXAMINER